



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: March 26, 2020

Subject: Efficacy Review for Excelyte Vet,
EPA Reg. No. 92108-1 (DP Barcode: 456939, E-Submission: 47790)

From: Kristen Willis, Chief
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To: Demson Fuller / Aline Heffernan
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Applicant: PCT LTD

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hypochlorous acid	0.046%
<u>Other Ingredients</u>	99.954%
Total.....	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-use liquid

Submission type: 320

Currently registered efficacy claim(s): hospital and healthcare disinfectant (bactericidal, virucidal, tuberculocidal, C. difficile) on hard, non-porous surfaces and sanitizer on food and non-food hard, non-porous surfaces.

Requested action(s): Add Emerging Viral Pathogen claim

Documents considered in this review:

- Cover Letter from applicant to EPA dated March 10, 2020

- Note: The cover letter identifies viruses that are not eligible to supporting emerging viral pathogens claims. Appropriate viruses are identified in the terms of registration letter.
- Data Matrix (EPA Form 8570-35) dated May 12, 2017
- Efficacy studies (MRID 49680706, 49680703)
- Proposed label dated March 10, 2020
- Terms of Registration letter March 14, 2020
- Efficacy Review for Reg. No. 92108-1 (DP 440982)
- Efficacy reviews for the cited product Reg. No. 82341-1 (DPs 428914 and 456904)

II STUDY CONCLUSIONS

MRID	Emerging virus claim	Organism(s)	Type of Virus (family)	Surface Type	Application Method(s) and/or Dilution	Contact Time	Soil load	Data support label claims?
49680703	Enveloped Viruses, large and small non-enveloped viruses	Feline calicivirus surrogate for Norovirus	Small, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	Yes
49680706	Enveloped Viruses, large and small non-enveloped viruses	Rhinovirus Type 16	Small, non-enveloped	Hard non-porous surface	RTU liquid	10 minutes	5% serum	Yes

III LABEL COMMENTS

Label Date: 3/10/2020

The terms of registration letter for the product, Excelyte Vet, EPA Reg. No. 92108-1, qualifies for an emerging viral pathogens claim.

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Norovirus
Large non-enveloped virus	Norovirus
Small non-enveloped virus	Norovirus; Rhinovirus type 16

These terms are **acceptable** as they are supported by the cited data. The claim on the proposed label is **not acceptable**. Please revise the claim on page 7 so that it **exactly** matches the following:

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

-Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Norovirus
Large non-enveloped virus	Norovirus
Small non-enveloped virus	Norovirus, Rhinovirus type 16

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or non-porous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard,

porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information."

Please make the following changes to the label the next time an amendment is submitted to the agency:

- 1) Throughout the label, revise directions for use for "heavily soiled" to "visibly soiled".
- 2) On page 6, remove the heading "Food-contact surface bacteria". The directions for use for food contact surfaces refer to a 1-minute contact time and not the 10 minute contact time listed for Listeria.
- 3) On page 11,
 - a. Remove references to EPA and CDC.
 - b. Revise the claims "This product meets AOAC efficacy testing requirements – or – standards for hospital disinfection" and "Meets AOAC germicidal spray standards for Hospital Grade Disinfectants". AOAC does not set efficacy testing standards. The claims may be revised to indicate the product was testing using those AOAC methods.
 - c. Claims for "germicidal" should be qualified according to the following:
<https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>
 - d. Remove "grade" from the following claims: "Hospital [grade] [level] Disinfectant" and "Veterinarian [grade] [level] disinfectant" as this implies heightened efficacy. See Chapter 12 of the label review manual;
<https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf>
 - e. Remove "defends against" from the claim "Disinfects [defends against] [common] household surfaces" as it implies protection from disease.
 - f. Remove "antiviral" from the following claim as it implies a drug use, "Effective against non-enveloped viruses* [[such as – or – e.g.,] [(] [norovirus], [rotavirus], [adenovirus], [)] [which] [are broadly antiviral and capable of inactivating both enveloped and non-enveloped viruses*]" "
 - g. Remove eliminates from the claim "Eliminate(s) bacteria – and/or – viruses* that hide [lurk] [reside] where you [touch] [breathe] [work] [play] [live]" or revise to reflect the log reduction achieved (e.g. 99.9%).
- d. On page 12,
 - i. Remove the claim "Fast acting disinfectant". Claims for fast are limited to products with a contact time of 30 seconds or less.
 - ii. Remove the claim "a new generation of protection" as it implies protection from disease.
 - iii. Remove "risk of" from the claim "Can help reduce the risk of cross contamination between treated hard, non-porous surfaces"
- e. On page 15, remove CPAP masks or specify external surfaces only.